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EXAMINER	
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ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,695	PIERCE ET AL.	
	Examiner	Art Unit	
	R. Michelle Vestal	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-16 and 18-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-16 and 18-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the amendment filed May 05, 2005, which papers have been placed of record in the file.

Claims 1, 3, 4, 16, 18 and 19 have been amended. Claims 2 and 17 have been canceled. Claims 1, 3-16 and 18-28 are pending and have been examined in this office action.

All previous rejections not set forth below have been withdrawn. It is Examiner's position that claims 1 and 16 contain new matter. If the amendments to these claims are withdrawn, then the rejections set forth in the office action dated March 03, 2005 will be reinstated.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 16 require the incorporation of both an enzyme and a mediator in the conductive track and/or the electrical contact of the working electrode, with the enzyme being *reactive* with the mediator. Although Applicant makes reference to incorporation of both an enzyme and a mediator in the conductive track and electrical contact of a working electrode (Table 1, V), on page 23, lines 7-21, Applicant states, "[i]n situations where the mediator is known to interact with the enzymes, the mediator and the enzyme *must be separated* during the preparation of the ink (emphasis added). For example, quinones are known to react with glucose dehydrogenase enzymes ....*Embedding the PQ mediator* in the conductive track enables the use of the quinoprotein enzyme-PQ mediator combination...." (emphasis added). Applicant clearly states that in situations where the enzyme and mediator react with each other (quinones and glucose dehydrogenase), only the mediator is embedded in the conductive track so that physical separation of the enzyme from the mediator before the start of the assay is achieved. This is contrary to the new limitations presented in claims 1 and 16 requiring the incorporation of both an enzyme and a mediator with the enzyme being reactive with the mediator.

Claims 5 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 5 and 20 disclose a biosensor further including at least one reagent-containing layer overlying *the conductive track leading from* the working electrode (emphasis added). Figures 1, 2, 4 and 5 clearly show the reagent-containing layer (22 and 22') overlying the working electrode (20 and 20'), not the conductive track (14a and 14a'). The specification also discloses the application of the reagent-containing layer on the surface of the working electrode (Page 13, lines 10-12 and Page 21, lines 21-25). No mention of applying the reagent-containing layer on the conductive track leading from the working electrode is made in the specifications, nor is there any explanation of how the positioning of the layer in this configuration would enable the detection of an analyte, because the conductive track is located outside of the sample reaction zone (Page 10, lines 5-9 and Page 16, lines 16-24) and, therefore, would not be exposed to the analyte.

For examination purposes, Claims 5 and 20 have been interpreted to limit the biosensor as further including at least one reagent-containing layer overlying the working electrode, as disclosed in the specifications.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Applicants remarks dated March 03, 2005, Applicant directs Examiner to look to page 4, line 34 through page 5, line 15 and page 16, line 30 through page 17, line 3 of the specification for support for the amendment to claims 1 and 16. These portions of the specification provide examples of representative enzymes, such as glucose oxidase and glucose dehydrogenase, and mediators, such as ferrocene, quinones, ferricyanide or ruthenium bipyridyl complexes. Although the mechanism by which the sensor operates is not disclosed by Applicant, it appears that Applicant wishes to limit the sensing mechanism of the biosensor utilizing an inherent oxidation/reduction reaction that occurs between the enzyme and the mediator with the application of an appropriate potential. For example, when ferrocene is used as a mediator in an enzymatic reaction of glucose with glucose oxidase, the reduced enzyme from the reaction of the enzyme with glucose is subsequently oxidized by the ferrocene with the application of an appropriate potential to regenerate the active catalyst. However, Applicant also discloses a situation where the enzyme itself is reactive with the mediator (page 23,

lines 7-21). It is unclear which "reaction" Applicant is referring to in amended claims 1 and 16. For examination purposes, the limitation that "the at least one enzyme being reactive with the at least one mediator" is interpreted as limiting the inherent sensing mechanism of the biosensor, as in the case with ferrocene and glucose oxidase.

Claims 1 (lines 14 and 17) and 16 (lines 18 and 21) recite the limitation "at least one reagent" and then further require at least one enzyme *and* at least one mediator. This is confusing because the specification indicates that an enzyme and a mediator are both considered reagents (page 7, lines 7-11), which would imply that the claim should require at least *two* reagents. For examination purposes, claims 1 and 16 have been interpreted as requiring at least two reagents.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,795,453 to Gilmartin.

Regarding Claim 1, Gilmartin discloses a biosensor (Col. 1, lines 6-10, 30-36 and Col. 1, line 63-Col. 2, line 3) having:

(a) an electrode support (Col. 2, lines 65-67 and Fig. 1, **D**);

(b) an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (Col. 2, lines 64-65, Col. 5, lines 47-50 and Fig. 1, **C**);

(c) a first conductive track leading from the working electrode to an electrical contact associated with the working electrode (Fig. 1, **A**) and a second conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 1, **A**). Component "A" in Figure 1 of Gilmartin refers to a "connecting strip," which is inserted into a spade connector to a potentiostat during operation (Col. 2, lines 61-62) to establish electrical connection to the electrodes. This connecting strip is interpreted as being a conductive track leading from the electrode and the end opposite the working area C constitutes the electrical contact to a potentiostat; and

(d) at least two reagents, comprising a mediator (Col. 4, lines 50-56) and an enzyme (Col. 10, lines 49-52), are incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact

associated with the working electrode or the electrical contact associated with the working electrode (Col. 2, lines 4-12, Col. 10, lines 49-52, Col 14, lines 16-35, Figs. 1 and 2). Figure 1 of Gilmartin shows an electrode assembly comprising a working area C of the electrode and a connecting strip A, which has been interpreted as a "conductive track" and an "electrical contact," as discussed previously. The shading of these components appears to indicate that the working area C and connecting strip A are made of the same material. Figure 2 shows the composition of the ink used to print the electrode assembly (the working area and the connecting strip), which includes a mediator. Accordingly, the mediator has been interpreted as being incorporated in the conductive track leading from the working electrode to the electrical contact associated with the working electrode and the electrical contact associated with the working electrode. Although Gilmartin discloses the sensing of hydrogen peroxide with the application of a certain potential (Fig. 2) as one embodiment, the biosensor comprises a metallo macrocyclic iron(II)/iron(III) complex, similar to a ferrocene (iron(II)/iron(III)) complex. The oxidation state of the iron complex mediator, which is dependent on the applied potential, determines the particular substance (the reduced form of glucose oxidase or the reaction product (hydrogen peroxide) of the reduced glucose oxidase and oxygen) to be "reacted" with the mediator. Accordingly, it is Examiner's position that the metallo macrocyclic mediator of Gilmartin would also be capable of reacting with glucose oxidase with the

application of an appropriate potential, although this is not the desired sensing mechanism embodied by Gilmartin.

Addressing Claim 3, Gilmartin discloses a biosensor wherein the mediator is selected from the group consisting of organometallic compounds, organic compounds, and coordination compounds with inorganic or organic ligands (Col. 8, line 18-Col. 9, line 40).

Regarding Claim 4, Gilmartin discloses a biosensor wherein the enzyme is selected from the group consisting of oxidases and dehydrogenases (Col. 10, lines 10-27 and lines 49-57).

Regarding Claim 5, Gilmartin discloses a biosensor further including at least one reagent-containing layer overlying the working electrode (Col. 9, lines 42-46).

Regarding Claim 8, Gilmartin discloses a biosensor wherein the working electrode has an area of from 0.5 mm^2 to 5 mm^2 (Col. 14, lines 44-47).

Addressing Claim 10, Gilmartin discloses a biosensor wherein the electrode arrangement further comprises a third electrode (Col. 16, lines 4-6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-16 and 18-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman in view of Gilmartin.

Regarding Claim 1, Feldman discloses a biosensor (Col. 1, lines 13-14) having:

(a) an electrode support (Col. 26, lines 25-26 and Fig. 2, **38**);

(b) an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (Col. 26, lines 22-23 and Fig. 2, **22** and **24**);

(c) a first conductive track leading from the working electrode to an electrical contact associated with the working electrode and a second conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. **2**, **22** and **24**); and

(d) at least one reagent incorporated in the working electrode (Col. 21, lines 28-31) comprising an enzyme (Col. 24, lines 18-43) and a mediator (Col. 15, line 20-Col. 24, line 15), the enzyme being reactive with the mediator (Col. 24, lines 30-33). Specifically, the enzyme can comprise glucose oxidase or glucose dehydrogenase (Col. 24, lines 27-28) and the mediator can comprise ferrocene (Col. 15, line 32), quinones (Col. 20, line 50-Col. 21, line 15), ferricyanide (Col. 22, line 28) or ruthenium bipyridyl complexes (Col. 15, lines 33-38).

Feldman does not disclose expressly that the biosensor has at least one reagent incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode or the electrical contact associated with the working electrode.

Gilmartin discloses a biosensor (Col. 1, lines 6-10, 30-36 and Col. 1, line 63-Col. 2, line 3) having at least one enzyme (Col. 10, lines 49-52) and one mediator incorporated throughout the working area of the electrode, the first conductive track leading from the working area of the electrode to the electrical contact associated with the working electrode and the electrical contact associated with the working electrode (Col. 2, lines 4-12, Col. 10, lines 49-52, Col 14, lines 16-35, Figs. 1, **A** and 2), thereby requiring only a single ink deposition step (Col. 10, lines 49-52 and Col. 20, lines 15-20). Component "A" in Figure 1 of Gilmartin refers to a "connecting strip," which is inserted into a spade connector to a potentiostat during operation (Col. 2, lines 61-62) to establish electrical connection to the electrodes. This connecting strip is interpreted as being a conductive track leading from the electrode and the end opposite the working area C constitutes the electrical contact to a potentiostat. Figure 1 of Gilmartin shows an electrode assembly comprising a working area C of the electrode and a connecting strip A, which has been interpreted as a "conductive track" and an "electrical contact," as discussed previously. The shading of these components appears to indicate that the working area C and connecting strip A are made of the same material. Figure 2 shows the composition of the ink used to print the electrode assembly (the working area and the connecting strip), which includes a mediator. Accordingly, the reagent (mediator) has been interpreted as being incorporated in the conductive track leading from the working electrode to the electrical contact associated with the working electrode and the electrical contact associated with the working electrode.

Feldman and Gilmartin are analogous art because they are from the same field of endeavor, that is electrochemical biosensors.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to have at least one reagent incorporated in the working area of the working electrode, the first conductive track leading from the working electrode to the electrical contact associated with the working electrode and the electrical contact associated with the working electrode of Gilmartin in the biosensor of Feldman because the need for multistep electrode and conductive track deposition is obviated, thereby simplifying the sensor manufacture and design, as taught by Gilmartin (Col. 10, lines 49-55 and Col. 20, lines 15-20). Gilmartin teaches that such an electrode assembly permits low voltage measurements of analytes which reduces noise, increases selectivity and increases the signal to noise ratio (Col. 2, lines 16-18). Gilmartin also teaches that the electrodes and electrode assemblies can be easily mass-produced and provide a universal platform on which assays can be performed (Col. 13, lines 47-53).

Therefore, it would have been obvious to combine Feldman with Gilmartin to obtain the invention as specified in claim 1.

Addressing Claim 3, Feldman discloses a biosensor wherein the mediator is selected from the group consisting of organometallic compounds, organic compounds, and coordination compounds with inorganic or organic ligands (Col. 15, lines 20-25).

Regarding Claim 4, Feldman discloses a biosensor wherein the enzyme is selected from the group consisting of oxidases and dehydrogenases (Col. 24, lines 21-27).

Regarding Claim 5, Feldman discloses a biosensor further including at least one reagent-containing layer overlying the working electrode (Col. 8, lines 53-55 and Fig. 2, 32).

Regarding Claim 6, Feldman discloses a biosensor requiring a low volume of sample to trigger an electrochemical reaction (Col. 7, lines 52-55).

Addressing Claim 7, Feldman discloses a biosensor wherein spacing between the working electrode and the at least second electrode does not exceed 200 micrometers (Col. 24, lines 66-67 and Col. 25, lines 1-3).

Regarding Claim 8, Feldman discloses a biosensor wherein the working electrode has an area of from 0.5 mm^2 to 5 mm^2 (Col. 49, lines 7-8).

Regarding Claim 9, Feldman discloses a biosensor wherein the electrode arrangement further comprises a trigger electrode (Col. 50, lines 60-61 and Col. 51, lines 1-12). Applicant discloses that a trigger electrode can be used to determine when

the sample has been applied to the strip, thereby activating the assay protocol (Page 10, lines 19-21). The trigger electrode prevents the assay from beginning until an adequate quantity of sample has filled the reaction zone (Page 10, lines 22-24). Feldman discloses a sensor including a fill indicator, such as an indicator electrode, that can be used to determine when the measurement zone or sample chamber has been filled (Col. 2, lines 64-67). An indicator electrode is defined as one or more electrodes that detect partial or complete filling of a sample chamber and/or measurement zone (Col. 7, lines 3-5). Therefore, Feldman's indicator electrode is interpreted to be synonymous with trigger electrode.

Addressing Claim 10, Feldman discloses a biosensor wherein the electrode arrangement further comprises a third electrode (Col. 49, lines 19-21).

Regarding Claim 11, Feldman discloses a biosensor wherein the electrode arrangement further comprises a fourth electrode, said fourth electrode having the function of a trigger electrode (Col. 51, lines 37-45).

Regarding Claim 12, Feldman discloses a biosensor further comprising an insulating layer overlying said electrode arrangement and said conductive tracks (Col. 8, lines 23-29 and Fig. 4, 40).

Regarding Claim 13, Feldman discloses a biosensor wherein a layer of mesh is interposed between the electrode arrangement and the insulating layer (Col. 29, lines 47-54).

Regarding Claim 14, Feldman discloses a biosensor wherein a capillary is interposed between the electrode arrangement and the insulating layer (Col. 26, lines 58-67 or Fig. 5, 26).

Regarding Claim 15, Feldman discloses a biosensor further comprising a layer of tape overlying said electrode arrangement and said conductive tracks (Fig. 2, 30).

Regarding Claim 16, Feldman discloses a biosensor (Col. 1, lines 13-14) having:

(a) a first substrate having two major surfaces (Fig. 1, 38 or Fig. 3, 38);

(b) a second substrate having two major surfaces (Fig. 1, 38 or Fig. 3, 38);

(c) a working electrode disposed on one major surface of the first substrate (Col. 3, lines 18-19, Fig. 1, 22 or Fig. 3, 22);

(d) at least a second electrode disposed on one major surface of the second substrate (Col. 3, lines 19-20, Fig. 1, 24 or Fig. 3, 24);

(e) a first conductive track leading from the working electrode to an electrical contact associated with the working electrode and a second conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 1, 22 and 24 or Fig. 3, 22 and 24);

(f) at least one reagent incorporated in the working electrode (Col. 21, lines 28-31) comprising an enzyme (Col. 24, lines 18-43) and a mediator (Col. 15, line 20-Col. 24, line 15), the enzyme being reactive with the mediator (Col. 24, lines 30-33). Specifically, the enzyme can comprise glucose oxidase or glucose dehydrogenase (Col. 24, lines 27-28) and the mediator can comprise ferrocene (Col. 15, line 32), quinones (Col. 20, line 50-Col. 21, line 15), ferricyanide (Col. 22, line 28) or ruthenium bipyridyl complexes (Col. 15, lines 33-38), all of which are cited by Applicant as representative enzymes and mediators (page 16, line 30-page 17, line 3).

(g) an insulating layer disposed between said working electrode and said at least second electrode (Col. 8, line 3-29, Fig. 1, 28 or Fig. 3, 28); and

(h) the major surface bearing the working electrode facing the major surface bearing the at least second electrode (Col. 2, lines 5-6, Fig. 1 or Fig. 3).

Feldman does not disclose expressly that the biosensor has at least one reagent incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode or the electrical contact associated with the working electrode.

Gilmartin discloses a biosensor (Col. 1, lines 6-10, 30-36 and Col. 1, line 63-Col. 2, line 3) having at least one reagent incorporated throughout the working area of the electrode, the first conductive track leading from the working area of the electrode to the

electrical contact associated with the working electrode and the electrical contact associated with the working electrode (Col. 2, lines 4-12, Col 14, lines 16-35, Figs. 1 and 2, and the rejection above), thereby requiring only a single ink deposition step (Col. 20, lines 15-20).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to have at least one reagent incorporated in the working area of the working electrode, the first conductive track leading from the working electrode to the electrical contact associated with the working electrode and the electrical contact associated with the working electrode of Gilmartin in the biosensor of Feldman because the need for multistep electrode and conductive track deposition is obviated, thereby simplifying the sensor manufacture and design, as taught by Gilmartin (Col. 10, lines 49-55 and Col. 20, lines 15-20). Gilmartin teaches that such an electrode assembly permits low voltage measurements of analytes which reduces noise, increases selectivity and increases the signal to noise ratio (Col. 2, lines 16-18). Gilmartin also teaches that the electrodes and electrode assemblies can be easily mass-produced and provide a universal platform on which assays can be performed (Col. 13, lines 47-53).

Therefore, it would have been obvious to combine Feldman with Gilmartin to obtain the invention as specified in claim 16.

Regarding Claim 18, Feldman discloses a biosensor wherein the mediator is selected from the group consisting of organometallic compounds, organic compounds, and coordination compounds with inorganic or organic ligands (Col. 15, lines 20-25).

Regarding Claim 19, Feldman discloses a biosensor wherein the enzyme is selected from the group consisting of oxidases and dehydrogenases (Col. 24, lines 21-27).

Regarding Claim 20, Feldman discloses a biosensor further including at least one reagent-containing layer overlying the working electrode (Col. 8, lines 53-55 and Fig. 2, 32).

Regarding Claim 21, Feldman discloses a biosensor requiring a low volume of sample to trigger an electrochemical reaction (Col. 7, lines 52-55).

Regarding Claim 22, Feldman discloses a biosensor wherein spacing between the working electrode and the at least second electrode does not exceed 200 micrometers (Col. 24, lines 66-67 and Col. 25, lines 1-3).

Regarding Claim 23, Feldman discloses a biosensor wherein the working electrode has an area of from 0.5 mm^2 to 5 mm^2 (Col. 49, lines 7-8).

Regarding Claim 24, Feldman discloses a biosensor wherein the electrode arrangement further comprises a trigger electrode (Col. 50, lines 60-61 and Col. 51, lines 1-12).

Regarding Claim 25, Feldman discloses a biosensor wherein the electrode arrangement further comprises a third electrode (Col. 49, lines 19-21).

Regarding Claim 26, Feldman discloses a biosensor wherein the electrode arrangement further comprises a fourth electrode, said fourth electrode having the function of a trigger electrode (Col. 51, lines 37-45).

Regarding Claim 27, Feldman discloses a biosensor wherein a layer of mesh is interposed between the electrode arrangement and the insulating layer (Col. 29, lines 47-54 or Fig. 1, 34).

Regarding Claim 28, Feldman discloses a biosensor wherein a capillary is interposed between the electrode arrangement and the insulating layer (Col. 26, lines 58-67 or Fig. 5, 26).

Claims 1, 3, 4, 10, 12, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes in view of Gilmartin.

Regarding Claim 1, Hughes discloses a biosensor (Col. 1, lines 5-6) having:

(a) an electrode support (Col. 2, line 10 and Fig. 1, **1**);

(b) an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (Col. 2, lines 11-12 and Fig. 1, **4**, **5** and **5a**);

(c) a first conductive track leading from the working electrode to an electrical contact associated with the working electrode and a second conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 1, **2**); and

(d) at least one reagent incorporated in the working electrode (Col. 4, lines 28-29) comprising an enzyme and a mediator (Col. 4, lines 40-42). Although Hughes does not disclose that the enzyme is reactive with the mediator, Hughes does disclose that the enzyme is glucose oxidase (Col. 4, lines 44-45) and the mediator is ferrocene (Col. 4, lines 45-46), which are cited by Applicant as a representative enzyme and mediator (page 16, line 30-page 17, line 3).

Hughes does not disclose expressly that the biosensor has at least one reagent incorporated in at least one of the first conductive track leading from the working electrode to the electrical contact associated with the working electrode or the electrical contact associated with the working electrode.

Gilmartin discloses a biosensor (Col. 1, lines 6-10, 30-36 and Col. 1, line 63-Col. 2, line 3) having at least one reagent incorporated throughout the working area of the electrode, the first conductive track leading from the working area of the electrode to the electrical contact associated with the working electrode and the electrical contact associated with the working electrode (Col. 2, lines 4-12, Col 14, lines 16-35; Figs. 1 and 2, and the rejection above), thereby requiring only a single ink deposition step (Col. 20, lines 15-20).

Hughes and Gilmartin are analogous art because they are from the same field of endeavor, that is electrochemical biosensors.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to have at least one reagent incorporated in the working area of the working electrode, the first conductive track leading from the working electrode to the electrical contact associated with the working electrode and the electrical contact associated with the working electrode of Gilmartin in the biosensor of Hughes because the need for multistep electrode and conductive track deposition is obviated, thereby simplifying the sensor manufacture and design, as taught by Gilmartin (Col. 10, lines 49-55 and Col. 20, lines 15-20). Gilmartin teaches that such an electrode assembly permits low voltage measurements of analytes which reduces noise, increases selectivity and increases the signal to noise ratio (Col. 2, lines 16-18). Gilmartin also

teaches that the electrodes and electrode assemblies can be easily mass-produced and provide a universal platform on which assays can be performed (Col. 13, lines 47-53).

Therefore, it would have been obvious to combine Hughes with Gilmartin to obtain the invention as specified in claim 1.

Addressing Claim 3, Hughes discloses a biosensor wherein the mediator is selected from the group consisting of organometallic compounds, organic compounds, and coordination compounds with inorganic or organic ligands (Col. 4, lines 44-45).

Regarding Claim 4, Hughes discloses a biosensor wherein the enzyme is selected from the group consisting of oxidases and dehydrogenases (Col. 4, lines 43-44).

Addressing Claim 10, Hughes discloses a biosensor wherein the electrode arrangement further comprises a third electrode (Col. 4, lines 20-23).

Regarding Claim 12, Hughes discloses a biosensor further comprising an insulating layer overlying said electrode arrangement and said conductive tracks (Col. 5, lines 25-26 and Fig. 1, 11).

Regarding Claim 13, Hughes discloses a biosensor wherein a layer of mesh is interposed between the electrode arrangement and the insulating layer (Col. 4, lines 53-54 and Fig. 1, 10).

Regarding Claim 15, Hughes discloses a biosensor further comprising a layer of tape overlying said electrode arrangement and said conductive tracks (Col. 5, lines 36-37 and Fig. 1, 13).

Response to Arguments

Applicant's arguments as they pertain to the rejection of claims 5 and 20 under 35 USC § 112, first paragraph have been fully considered but they are not persuasive. Applicant defines a reagent on page 7, lines 7-11 of the specification and neither silver nor silver chloride are listed as substances that are considered reagents nor would one possessing ordinary skill in the art consider these to be reagents. Accordingly, Applicant's alleged support for claims 5 and 20 is not persuasive and the rejection is maintained.

Applicant's arguments as they pertain to Gilmartin alone have been fully considered but they are not persuasive. Applicant appears to argue that there is an inherent reaction between certain mediators and enzymes because the arguments are

drawn to the particular sensing mechanism disclosed in Gilmartin. It is noted that traditionally the function of the mediator is to replace the oxygen that was required to oxidize the reduced form of the enzyme (glucose oxidase, for example) back to it's active form for the reaction with glucose. The sensing mechanism is dependent, however, on the application of an appropriate potential to make sure the mediator is in the appropriate oxidation state to react with the enzyme (for example, a potential is applied to ferrocene (an iron(II) complex) to generate an iron(III) complex, which then oxidizes the glucose oxidase back to its active form). Gilmartin utilizes an iron (II) mediator for a different purpose, the sensing of hydrogen peroxide with the application of an appropriate potential (to oxidize the iron (III) complex generated in the reaction with hydrogen peroxide back to an iron (II) complex). The sensing mechanism, and consequently the species being "reacted," is dependent on the oxidation state of the iron complex, which is determined by the potential applied to the electrode. Accordingly, the mediator of Gilmartin is presumably capable of reacting with the enzyme incorporated in the conductive track and the electrical contact of the working electrode, regardless of whether Gilmartin desired such a reaction. Anticipation only requires the capability to perform the specified function.

Applicant's arguments as they pertain to Gilmartin in combination with Feldman or Hughes have been fully considered but they are not persuasive. Both Feldman and Hughes disclose incorporation of a mediator, such as ferrocene, and an enzyme, such as glucose oxidase, in the working electrode of a glucose sensor (see rejections of

claims 1 and 16). As stated previously, glucose oxidase is an example of an enzyme that reacts with a mediator such as ferrocene, as alleged by Applicant (page 16, line 30-page 17, line 3). Gilmartin is relied on to teach that a mediator and an enzyme can also be incorporated in the conductive track leading from the working electrode and the electrical contact associated with the working electrode. One would be motivated to include the enzyme and mediator in the conductive track and electrical contact of the working electrode in order to simplify the manufacturing process by reducing the number of printing steps, as taught by Gilmartin (Col. 10, lines 49-52). Applicant has provided no real reason why Examiner is in error, therefore, the rejections based on the combination of Feldman with Gilmartin and the combination of Hughes with Gilmartin is maintained.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. Michelle Vestal whose telephone number is (571) 272-0524. The examiner can normally be reached on Monday-Friday, 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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rmv/ rmv
June 23, 2005

KAJ K. OLSEN
PRIMARY EXAMINER